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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/938,406	08/21/2001	George H. Lowell	484112.408D1	1965

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EXAMINER	
LUCAS, ZACHARIAH	
ART UNIT	**PAPER NUMBER**
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/938,406	LOWELL ET AL.	
	Examiner	Art Unit	
	Zachariah Lucas	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19 and 21-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19 and 21-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Currently, claims 19 and 21-35 are pending and under consideration in the application.

2. In the prior action, the Final action mailed on May 10, 2006, claims 3, 4, 6, 9-17, and 19-23 were under consideration and rejected.

3. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 8, 2007 has been entered.

In the Response of February 8, 2007, claims 3, 4, 6, 9-17 were cancelled; claim 19 was amended; and claims 24-35 were added.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. **(Prior Rejection- Maintained)** Claims 3, 4, 6, 10, 11, 16, 17, 19, and 21-23 were rejected under 35 U.S.C. 103(a) as being unpatentable over the teachings of the 292 patent or of Lowell (hereinafter, "the Lowell article," Science 240: 800-802), in view of VanCott (J Immunol

Methods 183: 103-17), and further in view WO 95/11700. Claims 3, 4, 6, 10, 11, 16, 17 have been cancelled from the application. The rejection is therefore withdrawn from these claims. In addition, new claims 24-26, and 28-35 have been added to the application. These claims correspond to previously pending claims 3, 4, 6, and 10-17. The limitations of these claims are taught by at least the 292 reference as has been previously described. See e.g., the action of April 5, 2004. The rejection is therefore extended to these claims.

The rejection is also extended to new claim 27. This claim corresponds to previously rejected claim 9, and requires that the gp160 antigen "consists essentially of the sequence set forth at residues 33-681 of SEQ ID NO: 1." Because it is not clear what the phrase "consists essentially of" is intended to exclude, particularly as independent claim 19 already requires that the protein has the molecular weight of about 140 kD (the same molecule weight as the indicated sequence of SEQ ID NO: 1), the claim is read only as narrowing claim 19 to embodiments wherein the truncated gp160 antigen comprises residues 33-681 of SEQ ID NO: 1. As was previously described, and is restated below, the application teaches that the 6D5 cells infected with the HTLV-III451 HIV strain inherently produce a truncated HIV gp160 protein having a molecule weight of about 140 kD. Page 21. The application also teaches that the gp160 obtained from these cells has the sequence of residues 33-681 of SEQ ID NO: 1. Pages 22-23. Because VanCott teaches gp160 antigens from the same cell line and infected by the same strain of HIV, the reference also inherently teaches a truncated HIV gp160 comprising the indicated sequence. Thus, the rejection is extended to new claim 27.

The rejection is therefore maintained over claims 19 and 21-35.

The Applicant traverses the rejection on four grounds. The Applicant first continues to argue that the cited prior art does not teach or suggest the use of a C-terminally truncated HIV gp160 antigen with a molecular weight of about 140 kD. Applicant next argues that the art does not teach that the truncated gp160 proteins would be capable of conjugating a proteosome without an added hydrophobic moiety. The Applicant's third set of arguments asserts that none of the cited references teaches an immunogenic composition meeting each of the claim limitations. Applicant's final argument is that non-obviousness is established by a demonstration that the conjugation of the truncated gp160 protein results in the production of neutralizing antibodies in mucosal secretions, whereas such was not seen by the administration of the gp160 protein alone.

With respect to Applicant's continued arguments regarding the nature of the "full-length" gp160 of the VanCott and Kalyanaraman references, the fact that these references did not recognize that the gp160 expressed by 6D5 cells infected with the HTLV-III451 HIV strain was a truncated protein with a molecular weight fails to overcome the rejection. As indicated by the Applicant on pages 21-22 of the application, this clone/HIV isolate combination inherently results in the production of the truncated gp140 protein, although the truncation "had not previously been recognized." Page 21, first full paragraph. Moreover, the Applicant admits in the application that gp160 proteins may have lower molecular weights depending on the clone and the isolate used. Id. Because the VanCott reference teaches the use of an HIV gp160 antigen that inherently meets the lower molecular weight and truncation limitations of the claims, it would have been obvious to those of ordinary skill in the art to have used the antigen disclosed therein. The fact that certain structural features of the expressed antigen were not recognized does not

render the use of the disclosed antigen any less obvious. The Applicant first argument is therefore not found persuasive for the reasons above, and the reasons of record.

The Applicant second argument, that those of ordinary skill in the art would reasonable expect that conjugation of the truncated gp160 protein with a proteosome would require that an exogenous moiety be conjugated to the antigen, is also not found persuasive. This argument was addressed in the prior action, where it was pointed out that both the Lowell article and the 292 patent teach the attachment of lauroyl to antigens such that they will form a complex with the proteosome. It is further noted that there is nothing in the claims to exclude such an additional hydrophobic moiety. In fact, claims 24 and 24 specifically require the presence of such a moiety. Thus, it is not clear how this argument is intended to distinguish the claimed invention from the prior art.

The third set of arguments, that neither of the 292 patent, the WO 95/11700 reference teach each of the claimed limitations, is also not found persuasive. These are arguments against the references individually. It has been clearly established that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The third argument is therefore also not found persuasive.

The applicant's final argument is that the claimed invention has the additional advantage of being capable of inducing the production of neutralizing antibodies in mucosal secretions. In support, the Applicant points to the teachings of VanCott, J Immunol 160: 2000-12 (1998). This argument is not found persuasive. As indicated previously, the art indicates that the

combination of the proteosomes and emulsions with an antigen, including HIV gp160 antigens, results in increased immunogenicity. See e.g., WO 95/11700, pages 35-36. Thus, the art provides motivation for the formulation of the gp160 of the VanCott reference cited in the rejection with proteosomes and emulsions- to increase the immunogenicity of the protein generally. The teachings of 1998 VanCott article indicate that an intranasal administration of the claimed composition was effective in the induction of a mucosal response. However, the reference provides no teachings that would indicate that those of ordinary skill in the art would not have expected the combination of gp160 with a proteosome and emulsion to achieve the improved immunogenicity for which the proteosomes and emulsions are indicated to provide in the cited references. The Applicant's later recognition of an additional advantageous use of the combination therefore fails to render the composition itself non-obvious. See e.g., MPEP 2145 II (indicating that a recognition of latent advantages that would naturally from following the suggestion of the prior art does not render a claimed invention non-obvious). In the present case, because the compositions suggested by the prior art would be capable of inducing such mucosal secretions if administered mucosally as was done in the 998 VanCott reference, the Applicant's assertion that the claimed composition are rendered non-obvious is not found persuasive.

Additional arguments are also presented with respect to claim 9. However, these arguments are based on the prior rejection against claim 9, requiring a modification of the protein of Desai. Upon further consideration of the facts of the case as described above, it appears that the previously applied VanCott reference also teaches the antigen of claim 27 (previously claim 9). Thus, Applicant's arguments regarding the modification of Desai are not found persuasive.

For the reasons above, and the reasons of record, the rejection is maintained.

6. **(Prior Rejection- Withdrawn)** Claim 9 was rejected under 35 U.S.C. 103(a) as being unpatentable over the 292 patent or the Lowell article, in view WO 95/11700, and further in view of Vancott and Desai. Claim 9 has been cancelled form the application, and replaced by new claim 27. In view of the extension of the rejection above to claim 27 (the replacement claim for claim 9), the rejection is withdrawn.

7. **(New Rejection)** Claims 19 and 21-35 are rejected under 35 U.S.C. 103(a) as being obvious over WO 95/11700 in view of the 292 patent, and further in view of U.S. 5,116,740 (the 740 patent). These claims have been described above. As was previously described, the combined teachings of WO 95/11700 and the 292 patent render obvious compositions comprising gp160 proteins with a proteosome and an emulsion. These two references do not teach a truncated gp160 protein according to claims 19 and 27. However, as was previously described, the application teaches that the claimed truncated gp160 proteins are inherently produced by 6D5 cells infected with the HTLV-III451 HIV strain. The same gp160 proteins are disclosed in the 740 patent. See, columns 2-3, and claim 2. While the reference does not teach that the resulting gp160 is the truncated gp160 of claim 27, the present application teaches that such truncation is inherent to the antigens produced by this cell line when infected with the indicated HIV strain. Because the reference discloses the use of the produced protein for the production of neutralizing anti-HIV antibodies (columns 1-2) it would have been obvious to those of ordinary skill in the art to substitute this protein for the antigen, particularly the gp160

antigen, suggested by the WO 95/11700 reference. The combined teachings of these references therefore render the claimed inventions obvious.

The applied 292 patent has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. **(Prior Rejection- Maintained)** Claims 3, 4, 9-17; 19, and 21-23 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 5, 7, and 8 of U.S. Patent No. 5,726,292 further in view of either of Anselem or WO 95/11700, and further in view of Vancott and Desai as described in the 103 rejection above. As indicated above, claims 3, 4, 9-17 have been cancelled, and replaced by new claims 24-35. The rejection is therefore maintained over claims 19 and 21-35. The Applicant traverses this rejection on the same grounds as asserted with respect to the 103 rejection over the 292 patent, in view of Vancott, and further in view WO 95/11700, above. The rejection is therefore maintained for the reasons indicated above.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Z. Lucas
Patent Examiner